NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES of AMERICA, et al., *Ex rel.* LAURIE SIMPSON Plaintiff/ Relator, v. BAYER CORPORATION; BAYER HEALTHCARE; PHARMACEUTICALS, INC.; BAYER HEALTHCARE, LLC; and BAYER AG, Defendants.	Civil Action No.: 05-3895 (JLL) **OPINION**

This matter comes before the Court by way of a motion to dismiss Plaintiff Laurie Simpson's ("Relator", "Simpson", or "Plaintiff")'s Seventh Amended Complaint (hereafter "Complaint") pursuant to Federal Rules of Civil Procedure 12(b)(1), 12(b)(6) and 9(b) filed by Bayer Corporation, Bayer HealthCare Pharmaceuticals, Inc., and Bayer HealthCare LLC (collectively "Bayer") (CM/ECF No. 116).[1] The Court decides the motion without oral argument pursuant to Federal Rule of Civil Procedure 78.

The Court has considered the parties' submissions, and for the reasons set forth below, denies the motion in part and grants the motion in part.

[1] The motion is not brought on behalf of Bayer AG, a named defendant which has never been served with process. (Def.'s Mot. 1 n.1).

I. BACKGROUND[2]

Relator Simpson, a former employee of Bayer, brings this *qui tam* suit in connection with Defendant Bayer's alleged conduct in connection with two drugs, Trasylol[3] and Avelox[4]. Specifically, "[t]his Complaint arises from Bayer's concealment of safety risks, unlawful marketing, and kickbacks associated with its illegal on and off-label promotion of the prescription drug Trasylol and the kickbacks associated with its illegal on and off-label promotion of Avelox." (Compl. ¶ 1).

Plaintiff was employed by Bayer from April 1998 through January 2005. (Compl. ¶ 78). Throughout that time she held various marketing and analytical positions, primarily related to the drugs Trasylol and Baycol. *Id.*

Plaintiff alleges that a substantial portion of Trasylol's use was "off-label," or "for a use other than the one approved by the FDA." (Compl. ¶ 91 n.10). Trasylol was associated with dangerous risks, "including hypersensitivity and anaphylaxis, heart attack, adverse graft patency and clotting, and renal dysfunction." (Compl. ¶¶ 93, 102, 111-14, 142, 148-49). Simpson further alleges that many of these risks were increased through off-label uses. Notwithstanding, Bayer allegedly downplayed these risks and promoted Trasylol as having various health benefits. (Compl. ¶¶ 99-100, 102-07, 109-10, 120, 129, 134, 152-55). Not only did Bayer allegedly market off-label uses, but Bayer allegedly paid kickbacks to increase use of Trasylol. (Compl. ¶¶ 127-82). After Simpson

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[2] The Court accepts the allegations in the Complaint as true for the purposes of the instant motion.

[3] "Trasylol is Bayer's trade name for aprotinin, a drug approved for administration during cardiac surgery to prevent excess bleeding. The United States Food and Drug Administration ("FDA") approved Trasylol for the limited purpose of reducing blood loss in the course of coronary artery bypass graft ("CABG") surgeries." (Compl. ¶ 2).

[4] "Avelox is Bayer's trade name for moxifloxacin hydrochloride, an extremely powerful antibiotic." (Compl. ¶ 3).

left Bayer, the FDA allegedly requested that Bayer suspend marketing of the drug, and it was recalled from the market in 2008. (Compl. ¶¶ 9, 11).

In addition, Bayer allegedly employed various kickback schemes to increase Avelox prescriptions by physicians. (Compl. ¶¶ 216, 218-51). Simpson alleges that she observed Bayer's promotional practices through her peripheral involvement with the drug's marketing. (Compl. ¶¶ 84-85).

Simpson also alleges that Bayer unlawfully retaliated against her for expressing concerns about Baycol and later about Trasylol, which included "harassment, discrimination, and other negative employment actions." (Compl. ¶ 261). Simpson allegedly expressed concern about the safety of Baycol to her managers. (Compl. ¶ 264). Bayer eventually withdrew Baycol from the market. (Compl. ¶ 268).

Simpson kept "voluminous files" which contained damaging documents. (Compl. ¶ 269). Multiple members of the senior management team expressed disappointment that Simpson kept those files in view of then-pending multi-district litigation concerning Baycol. (Compl. ¶ 271). One senior manager expressed anger to Simpson when she called attention to certain damaging documents not produced in related discovery. (Compl. ¶ 271). Simpson allegedly experienced overwhelming emotional distress as a result of assisting in the defense of Baycol suits while knowing that the drug caused avoidable patient deaths. (Compl. ¶ 272). As a result, Simpson had difficulty sleeping and frequent nightmares. (Compl. ¶ 273).

After Bayer withdrew Baycol from the market, Simpson was reassigned to work on Trasylol. (Compl. ¶ 275). Learning of Bayer's allegedly fraudulent and illegal marketing practices with respect to that drug allegedly exacerbated her emotional

distress. (Compl. ¶ 277). Simpson allegedly complained to her supervisor that she would not participate in efforts to disguise as valid certain meetings that Simpson believed to be a cover for improper and illegal kickbacks to prescribers to boost Trasylol sales. (Compl. ¶¶ 278, 280). She also complained to other Bayer employees. (Compl. ¶ 279). Simpson alleges that as a result, she was barred from participating in team activities and her application for a project manager job was ignored. (Compl. ¶¶ 281-282).

As Bayer increased its off-label marketing of Trasylol, Simpson became more concerned and requested a meeting with her supervisor as well as Dean Slack, Director of the Strategic Analysis Department. (Compl. ¶ 286). During the meeting, Simpson allegedly expressed her view that certain aspects of Bayer's marketing, namely Cardiac Team Meetings were "fraudulent, promotional in nature, involved kickbacks, violated Bayer's Corporate Compliance policy, and were illegal." (Compl. ¶ 286). Despite allegedly speaking to an in-house attorney as well as Stan Horton, Director of Marketing for Trasylol, Plaintiff does not believe any actual changes were made. (Compl. ¶ 287). Instead, Simpson was allegedly excluded from the business planning process for Trasylol in favor of two unqualified members of the department. (Compl. ¶ 287). Bayer subsequently instituted a policy to address the allegedly illegal marketing efforts, which was ignored, while senior management again referred to the Cardiac Team Meetings as market research and proposed concealing safety information. (Compl. ¶¶ 288-90). All the while, Simpson continued to endure substantial additional stress. (Compl. ¶ 291).

In July 2004, Simpson learned that in lieu of her, a less qualified colleague was promoted into a newly created and unadvertised position. (Compl. ¶ 293). Simpson was informed that "they [*i.e.*, Bayer] would have found a way to disqualify [her] even if she

had applied." (Compl. ¶ 293). Simpson continued to indicate to senior management that "she would not support, condone, or otherwise enable behavior she considered to be fraudulent." (Compl. ¶ 294). In August 2004, Mr. Horton, Director of Marketing for Trasylol, indicated that he needed a market researcher who was going to be "supportive." (Compl. ¶ 294). Simpson indicated that she was willing to be "supportive" but not inasmuch as that required lying or covering up what she considered to be fraudulent conduct. (Compl. ¶ 294). One month later, Simpson was notified that she was being terminated because of a workforce reduction. (Compl. ¶ 295). However, her job function was not eliminated; rather, a less qualified employee assumed that role. (Compl. ¶ 296). Simpson's supervisor stated that she felt Simpson was being terminated because she "stood up to Stan [Horton]." (Compl. ¶ 296). Simpson also indicated to a member of the Human Resources Department that her termination was illegal. (Compl. ¶ 297).

The operative Complaint contains 39 causes of action, which fall into the following general categories: (1) violation of the federal False Claims Act, 31 U.S.C. §§ 3729-3733 ("FCA"), through marketing and sales of Trasylol (Counts 1-8); (2) violation of the FCA due to the payment of kickbacks by Bayer to promote Trasylol and Avelox (Counts 9-12); (3) violations of a number of state and city false claims acts (Counts 13-25)[5]; and (4) employment related claims including workplace retaliation (Counts 36-37) and intentional infliction of emotional distress (Counts 38-39).

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[5] California False Claims Act, Cal. Govt. Code §§ 12650, *et seq.*; Delaware False Claims and Reporting Act, 6 Del. C. §§ 1201, *et seq.*; Florida False Claims Act, Fla. Stat. §§ 68.081, *et seq.*; Georgia False Medicaid Claims Act, O.C.G.A. §§ 49-4-168, *et seq.*; Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21, *et seq.*; Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §§ 175/1, *et seq.*; Indiana False Claims and Whistleblower Protection Act, In. Code §§ 5-11-5.5, *et seq.*; Louisiana False Claims Act/Medical Assistance Programs Integrity Law, 46 La. Rev. Stat. Ch. 3 §§ 437.1, *et*

As pointed out by Bayer in its motion, Simpson has amended her complaint seven times. (Def.'s Mot. 2). The Government declined to intervene on February 19, 2010 (CM/ECF No. 16). No state or city has taken a position on intervention. (Def.'s Mot. 2).

Although the United States declined to intervene, it filed a Statement of Interest in connection with the instant motion on June 18, 2013. (CM/ECF No. 117). With previous permission from the Court, Bayer responded to the Government's Statement of Interest on June 28, 2013 (CM/ECF No. 125) and Plaintiff filed a response on July 8, 2013 (CM/ECF No. 126).[6]

II. LEGAL STANDARD

Unless otherwise noted, the applicable legal standard is one for a motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure12(b)(6).

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seq.; Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §§ 5A, *et seq.*; Michigan Medicaid False Claims Act, MCLS §§ 400.601, *et seq.*; Montana False Claims Act, Mont. Code §§ 17-8-401, *et seq.*; Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010, *et seq.*; New Hampshire Medicaid Fraud and False Claims Law, N.H. Rev. Stat. Ann. §§ 167:61, *et seq.*; New Mexico Fraud Against Taxpayers Act, N.M.S. §§ 44-9-1, *et seq.*; New York False Claims Act, N.Y. Fin. Law §§ 187, *et seq.*; Oklahoma Medicaid False Claims Act, Okla. Stat. Ann. §§ 5053, *et seq.*; Rhode Island False Claims Act, R. I. St. §§ 9-1.1-1, *et seq.*; Tennessee Medicaid False Claims Act, Tenn. Code §§ 71-5-181, *et seq.*; Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code §§ 36.001, *et seq.*; Virginia Fraud Against Taxpayers Act, Va. Code §§ 8.01-216.1, *et seq.*; Wisconsin False Claims Act, Wis. Stat. Ann. §§ 20.931(1), *et seq.*; District of Columbia False Claims Act, D.C. Code §§ 2-308.03, *et seq.*; and New York City False Claims Act, N.Y.C. Admin. Code, §§ 7-801, *et seq.* (Compl. ¶¶ 8a-w).

[6] The Court notes that without previous permission, Bayer filed a letter further responding to Plaintiff's reply to its response to the Government's Statement of Interest, reasoning that Plaintiff attached a new exhibit and raised certain new arguments in her July 8, 2013 submission. (CM/ECF No. 127). By way of letter dated July 15, 2013, Plaintiff objected to the Court's consideration of same. (CM/ECF No. 128). Defendant filed a final letter indicating that it did not object to Plaintiff filing a further response. (CM/ECF No. 129). However, in light of the extensive briefing in this case generally, as well as in response to the Government's Statement of Interest, the Court declines to consider Bayer's July 15, 2013 submission (CM/ECF No. 127) and therefore Plaintiff's request to file an additional response is moot.

Federal Rule of Civil Procedure 8(a)(2) requires that a complaint set forth "a short and plain statement of the claim showing that the pleader is entitled to relief." For a complaint to survive dismissal, it "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). The plaintiff's short and plain statement of the claim must "give the defendants fair notice of what the . . . claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 545 (quoting *Conley v. Gibson*, 355 U.S. 41, 47, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957)).

In evaluating the sufficiency of a complaint, a court must accept all well-pleaded factual allegations as true and draw all reasonable inferences in favor of the non-moving party. *See Phillips v. County of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008). "Factual allegations must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. at 555 (2007). Further, "[a] pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do. Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Iqbal*, 556 U.S. at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. at 555, 557 (2007)). However, this "'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element." *West Penn Allegheny Health Sys. Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010) (quoting *Phillips v. County of Allegheny,* 515 F.3d 224, 234 (3d Cir.2008)).

III. DISCUSSION

The Third Circuit has explained, "[i]n broad strokes, the FCA imposes penalties on persons who knowingly submit fraudulent claims to the government. To encourage the ferreting out of fraud against the government, the FCA incentive[izes] private individuals aware of such fraud to bring civil actions as relators against those submitting such claims by allowing relators to collect a percentage of any recovery." *United States ex rel. Paranich v. Sorgnard*, 396 F.3d 326, 332 (3d Cir. 2005).[7]

In support of its motion to dismiss, Bayer makes the following primary arguments: (1) the Court lacks subject matter jurisdiction over most of Simpson's FCA counts; (2) Simpson's misbranding allegations fail to state a claim; (3) all of Simpson's FCA counts should be dismissed because she has not pled causation or identified any purportedly false claims; (4) Plaintiff's state and local FCA counts should be dismissed; (5) any surviving counts must be cabined by limitations periods and the effective dates of statutes; and (6) Simpson's employment counts should be dismissed. (CM/ECF No. 116-1).

At the outset, the Court notes that the Government "takes no position on Bayer's arguments concerning the Court's subject matter jurisdiction, Simpson's state and local claims, the statutes of limitation, or Simpson's employment related claims." (Gov. SOI, 1). Rather, the Government's Statement of Interest concerns only the following: (1) the circumstances under which the marketing of prescription drugs or violations of the Anti-

[7] "Prior to filing such a civil action, known as a *qui tam* action, the relator must disclose the information regarding the fraud to the government. The government then has sixty days to intervene and take over the action. *See* 31 U.S.C. § 3730(b). If the government does not do so, the relator may continue with the action unless the FCA's jurisdictional bar provision is triggered." *Paranich*, 396 F.3d at 332.

Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, may give rise to an actual FCA claim; (2) whether reimbursement under a Diagnosis Related Group (DRG) precludes liability under the FCA; and (3) the proper standard for assessing the sufficiency of Simpson's misbranding and AKS claims under Federal Rule of Civil Procedure 9(b). (Gov. SOI 1-2). As the Court's subject matter jurisdiction goes to its power to hear a case, it will begin its analysis there.

1. Subject Matter Jurisdiction

Pursuant to Federal Rule of Civil Procedure 12(b)(1), a court must dismiss a complaint if it lacks subject matter jurisdiction to hear a claim. In contrast to a 12(b)(6) motion to dismiss for failure to state a claim, in a challenge to the court's jurisdiction under 12(b)(1), "[t]he plaintiff has the burden of persuasion to convince the court it has jurisdiction." *Gould Elec. Inc. v. United States*, 220 F.3d 169, 178 (3d Cir. 2000) (citing *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir. 1991)).

Motions to dismiss under Rule 12(b)(1) may be treated as either a "facial or factual challenge to the court's subject matter jurisdiction." *Gould*, 220 F.3d at 176. Under a facial attack, the movant challenges the legal sufficiency of the claim and the Court considers only "the allegations of the complaint and documents referenced therein and attached thereto in the light most favorable to the plaintiff." *Id.* In reviewing a factual attack, however, the challenge is to the actual alleged jurisdictional facts. In that instance, a court is free to consider evidence outside of the pleadings. *Id.* As Defendant lodges a factual attack in this case, the Court may consider evidence outside the pleadings.

The Third Circuit has explained that "[u]nder certain circumstances, the [False Claims Act's] *qui tam* provisions allow private relators to sue, on behalf of the United States, any person or entity that submits a false claim to the Government." *United States ex rel Atkinson v. Pa. Shipbuilding Co.*, 473 F.3d 506, 518 (3d Cir. 2007). Generally, in the FCA context, a district court does not have jurisdiction over claims based upon publicly disclosed information unless an individual relator is an "original source" of the information which forms the basis of a false claims act suit. *United States ex rel. Mistick PBT v. Housing Authority of City of Pittsburgh*, 186 F.3d 376, 388 (3d Cir. 1999) (quoting 31 U.S.C. § 3730(e)(4)(A)). The "public disclosure bar" will apply and divest a court of jurisdiction if the following elements are met:

> (1) there was a "public disclosure";
> (2) "in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government [General] Accounting Office report, hearing, audit, or investigation, or from the news media";
> (3) of "allegations or transactions" of the fraud;
> (4) that the relator's action was "based upon"; and
> (5) the relator was not an "original source" of the information.

United States ex rel. Paranich v. Sorgnard, 396 F.3d 326, 332 (3d Cir. 2005). *United States ex rel. Dunleavy v. County of Delaware*, 123 F.3d 734, 738 (3d Cir. 1997) *abrogated on other grounds by Graham County Soil and Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280 (2010). The linchpin is "whether the publicly disclosed information 'could have formed the basis for a governmental decision on prosecution, or could at least have alerted law-enforcement authorities to the likelihood of wrongdoing.'" *United States ex rel. Settlemire v. District of Columbia*, 198 F.3d 913, 918 (D.C.Cir. 1999) (quoting *Springfield Terminal*, 14 F.3d 654, 654 (D.C.Cir. 1994)).

The analysis begins by determining whether a relator's allegations are based on "publicly disclosed allegations or transactions." *Atkinson*, 473 F.3d at 519. The inquiry consists of two steps. "First, [the court] must determine whether the information was disclosed via one of the sources listed in § 3730(e)(4)(A)." *Id.* Second, the court considers whether the relator's allegations are based on those public disclosures. "[T]o be 'based upon' the publicly revealed allegations or transaction the complaint need only be 'supported by' or 'substantially similar to' the disclosed allegations and transactions." *Id.* (quoting *Mistick*, 186 F.3d at 385-88). If so, in order to establish subject matter jurisdiction, a plaintiff must be an "original source." *Id.*[8]

Bayer argues that the Court lacks subject matter jurisdiction to hear all of Plaintiff's claims concerning Avelox because there were previous public disclosures and she is not an original source; specifically, public allegations of kickbacks predated this lawsuit and Simpson testified that she did not work on that drug.[9] (Def.'s Mot. 2, 8).

As discussed above, the information may not have been disclosed via a source listed in § 3730(e)(4)(A).[10] Bayer points to two types of sources which it contends

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[8] An "original source" is: "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. 3730(e)(4)(B); *Atkinson*, 473 F.3d at 518.

[9] In its moving brief, Defendant also argues that the Court lacks subject matter jurisdiction over most of Simpson's claims concerning Trasylol. However, for purposes of the instant motion, Bayer withdraws its jurisdictional motion as to Trasylol "[b]ecause this case is eight years old and Bayer's jurisdictional arguments would not dispose of all Trasylol claims." (Def.'s Reply 9).

[10] 31 U.S.C. § 3730(e)(4)(A) lists the following sources: "(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media . . . ."

constitute "news media": (1) internet postings; and (2) media reports. (Def.'s Mot. 9-12). In her Opposition, Simpson characterizes the sources to which Bayer points as anonymous postings in an online chat room and a laudatory article in a healthcare periodical, and argues that the "public disclosures" to which Bayer points do not meet the jurisdictional bar. (Pl.'s Opp'n. 1, 8-18). The Court will address each.

A. Postings in Online Forums

With regard to the web postings, Bayer points to two postings on separate websites which it contends predate Simpson's Avelox related counts and are identical to her allegations that Bayer paid kickbacks to induce Avelox prescriptions. (Def.'s Br. 10-11). Defendant points to the following anonymous postings in response threads on online forums. First, the following was posted on www.cafepharma.com:

> On December 2, 2004, a posting on CaféPharma in a thread entitled "Avelox Litigation?" contended that Bayer "offer[ed] bribes and financial kickbacks to the doctors for prescribing the drug [Avelox] .... Oh yeah by the way, when that happens it is a violation of Federal laws." CaféPharma "Avelox Litigation?" Thread (Ex. G) at Post No. 38.[11]

(Def.'s Br. 10). Second, Bayer points to the following posting on www.healthboards.com:

> On July 31, 2004, a posting on HealthBoards discussing Avelox and two other medicines alleged, "The reason why they are heavily prescribed, is that Bayer, and other pharmaceutical firms, basically bribe doctors into dolling this stuff out, when a less dangerous drug . . . would be far more appropriate. My sister-in-law is a drug rep, so I know how it all works."

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[11] *Available at:* http://www.cafepharma.com/boards/showthread.php?t=22749. Defendant characterizes CaféPharma as "an internet site that is accessible to the general public and intended for use by pharmaceutical sales representatives to discuss job-related issues." (Def.'s Br. 10 n. 7). *See generally* http://www.cafepharma.com.

HealthBoards "I fired my doctor today....chronic sinusitis" Thread (Ex. H) at Post No. 4.[12]

(Def.'s Br. 10). Defendant argues that the websites at issue here, "which are well-established, available to the general public, and easy to find, published the same claim Simpson now makes—that Bayer allegedly paid illegal Avelox kickbacks." (Def.'s Reply 5). On the other hand, Simpson argues that those postings do not qualify as news media.

Plaintiff contends that the websites on which Defendant rely do not qualify as news media, characterizing "CaféPharma, [as] a forum for pharmaceutical workers to schmooze and vent, and HealthBoards, [as] a forum for patients to give each other support." (Pl.'s Opp'n. 11). Further, Relator maintains that "[n]either site is designed to convey *news* to the public or to the government; they simply do not match the ordinary meaning of "news media" or the purpose of the public-disclosure bar." (Pl.'s Opp'n. 12) (emphasis in original) (citing *Graham County*, 130 S.Ct. at 1407) ("Congress . . . [enacted] the public-disclosure bar in an effort to strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits.").

The Supreme Court recently noted that "[t]he other sources of public disclosure in § 3730(e)(4)(A), especially 'news media,' suggest that the public disclosure bar provides 'a broa[d] sweep.'" *Schindler Elevator Corp. v. Unites States ex rel. Kirk*, --- U.S. ---, 131 S.Ct. 1885, 1891 (2011) (quoting *Graham County*, 130 S.Ct. at 1404) (alteration in original). However, while it is certainly the case that websites may constitute news

[12] *Available at* http://www.healthboards.com/boards/sinus-problems/194523-i-firedmy-doctor-today-chronic-sinusitis.html. Bayer describes HealthBoards as "a support group internet site accessible by the general public." (Def.'s Br. 10 n. 8). *See generally* http://www.healthboards.com.

media in certain instances, not everything posted on the internet qualifies. *Green*, 843 F. Supp. 2d 20, 32-33 (D.D.C. 2012); *United States ex rel. Repko v. Guthrie Clinic, P.C.*, No. 04-1556, 2011 WL 3875987 (M.D. Pa Sept. 1, 2011) *aff'd.* 490 F. App'x 502, 504 (3d Cir. 2012). Accordingly, the Court concludes that a case-by-case approach is more appropriate.

Under the facts of the instant case, the informal message boards and community forums here are distinguishable from the online sources at issue in the cases on which Bayer relies. (Def.'s Mot. 10) (citing *Repko*, 2011 WL 3875987 (concluding that information on the following websites constituted a public disclosure: website which worked to "gather and publicize information about nonprofit organizations"; one which billed itself as "the leading source of information about philanthropy worldwide," which contained a comprehensive database; information for investors on the Standard and Poors website; and the Bloomberg Professional website which "provid[ed] acces to all the news, analytics, communications, charts, liquidity, functionality and execution services" to assist investors)); *Green v. Serv. Contract Educ. and Training Trust Fund*, 843 F. Supp. 2d at 32-33 (page on contractor website which was designed to promote relevant information and was visited by "thousands of professionals in the government services industries" constituted public disclosure)). For example, the sources involved in *Repko* were well recognized or industry specific outlets which contained articles, a comprehensive database, and a number of other tools geared toward the dissemination of reliable information. 2011 WL 3875987, at *8. Unlike an article on a website maintained by a recognized news outlet, a trade journal, or even a promotional website geared toward the dissemination of information, the anonymous postings in this case

amounted to nothing more than vague allegations in an informal forum discussion without any indicia of reliability or substantiation. Healthboards.com holds itself out an online group support community.[13] Similarly, although the homepage of cafépharma.com contains a section entitled "current news," the posting on which Bayer relies is on the message board portion of the site.[14]

The Supreme Court observed in *Graham County* that the public disclosure bar was "an effort to strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits." 130 S.Ct. at 1407. Here, it would undermine that balance to treat as news media the anonymous contributions to informal discussions on community web forums or message boards at issue in this case. Despite the fact that Defendant correctly characterizes the websites at issue here as easy to find, well-recognized, and publicly available, it remains that the character and substance of the postings at issue are more akin to an informal message board and web forum, not geared

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[13] The "About Us" portion of the HealthBoards website reads: "Dealing with a medical condition is often difficult. Connecting with others who are going through the same thing can make a world of difference. HealthBoards.com is where you can make those connections. HealthBoards provides a unique one-stop support group community offering over 200 message boards on various diseases, conditions, and health topics. The HealthBoards community is one of the largest and most dynamic on the Web, with over 10 million monthly visitors, 850,000 registered members, and over 4.5 million messages posted. HealthBoards was rated as one of the top 20 health information websites by Consumer Reports Health WebWatch." Available at: http://www.healthboards.com/about.php (last visit August 18, 2013). Similarly, the Frequently Asked Questions ("FAQ") section explains, in relevant part, as follows: "Blog and Message Board Differences . . . Message Boards are for asking questions and interacting with the regular members. Blogs are only for journaling your own board topic related experience." Available at: http://www.healthboards.com/boards/faq.php?faq=faq_hb#faq_poliguid (last visit August 18, 2013) (emphasis omitted).

[14] The Court need not reach the issue of whether "current news" postings on websites like cafepharma.com would constitute "news media" for purposes of the FCA.

toward the dissemination of "news." Therefore, the Court concludes that the two anonymous postings in the online forums at issue in this case did not provide "sufficient information in the public sphere to put the government on notice of the potential presence of fraud." *United States ex rel. Schumann v. AstraZeneca PLC*, No. 03-5423, 2010 WL 4025904, at *5 (E.D. Pa. Oct. 13, 2010).

B. Medical Media and Marketing Article

In addition, Bayer argues that Simpson's allegations were disclosed in news media reports before Simpson asserted her Avelox counts. (Def.'s Mot. 11-12).[15] Specifically, Defendant points to an August 2002 article published in *Medical Media and Marketing*. (Def.'s Mot. 11, Ex. I). The parties do not dispute that this source constitutes news media for purposes of the FCA's jurisdictional bar. However, Bayer argues that "[t]his article provides the essential elements of Simpson's alleged fraud: a description of certain true facts and other facts that Simpson believes were illegal—*i.e.*, Bayer's alleged subsidizing of physician participation in promotional activities in the guise of educational programs." (Def.'s Mot. 12) (citing *Atkinson*, 473 F.3d at 519).

The appropriate inquiry is whether "the current action is 'based upon' the public disclosure of the allegations or transaction of fraud. . . [T]he term 'based upon' means 'supported by' or 'substantially similar to,' not 'actually derived from.'" *Paranich*, 396 F.3d at 334. Bayer asserts that the article, entitled "What's ROI got to do with CME?", "concerned use of physician education programs to boost sales and described Bayer's use

[15] Bayer maintains that "Simpson's allegations are substantially similar to and supported by the public postings on these public websites." (Def.'s Mot. 11). However, as the Court determined that the particular web forums to which Bayer points do not constitute public disclosures within the meaning of the FCA, it need not address that argument.

of ROI analysis to evaluate its 'support' in developing three interactive on-line programs concerning respiratory diseases." (Def.'s Mot. 11-12). On the other hand, Simpson argues that the article discloses "mere ancillary facts" regarding a Bayer-supported online "CME," not the essential elements of its fraudulent scheme relating to Avelox. (Pl.'s Opp'n. 12). Further, Plaintiff argues that "nowhere does [she] allege that Bayer's funding of CMEs can be inferred to be improper merely because Bayer attempted to determine the 'cost-verses-benefit' of these courses. Instead, Simpson alleges that Avelox CMEs were improper because Bayer, for example, used biased vendors under the guise of impartiality and gave out free textbooks and free dinners." (Pl.'s Opp'n. 13). In addition, Simpson argues that "biased CMEs were but one of a long list of Avelox-related kickbacks" alleged in the SAC. (Pl.'s Opp'n. 13).

Having considered the article at issue, the Court agrees with Simpson that it does not reveal the essential elements of the alleged fraudulent scheme relating to Avelox; rather, the article generally describes three of Bayer's "online case presentations of the diagnosis and management of respiratory diseases." (Def.'s Mot. Ex. I, 5-6). While the article does cite the success of these CMEs, it does not mention kickbacks or otherwise indicate that the use of those programs is fraudulent. Therefore, as the relevant article neither sets out the allegations advanced in the *qui tam* action nor all of the essential elements of Simpson's claims, the action is not "based upon" the Medical Media and Marketing Article. *Mistick*, 186 F.3d at 388 ("a *qui tam* action is 'based upon' a qualifying disclosure if the disclosure sets out either the allegations advanced in the *qui tam* or all of the essential elements of the *qui tam* action's claims.").

In sum, as the Court concludes that Simpson allegations were not based on "publicly disclosed allegations or transactions," her FCA claim is not subject to the jurisdictional bar of § 3730(e)(4)(A). Therefore, the Court need not consider whether Simpson is an original source. *Atkinson*, 473 F.3d at 519.

2. Failure to State a Claim

Bayer asserts that Simpson's misbranding allegations fail to state a claim for two primary reasons: (1) alleging a regulatory violation is not sufficient to state a claim under the FCA; and (2) because of the way the Government reimburses providers for in-patient care, Simpson cannot establish that Trasylol use was material to the submission of provider claims for payment. As the Court finds that dismissal is warranted in this case due to the former, it does not reach the parties' arguments regarding materiality in light of the Government's reimbursement methods.

First, "to plead a claim upon which relief could be granted under a false certification theory, either express or implied, a plaintiff must show that compliance with the regulation which the defendant allegedly violated was a condition of payment from the Government." *Wilkins*, 659 F.3d at 309. The Court agrees with Defendant that Plaintiff does not sufficiently connect the alleged violations to false claims for payment. Defendant argues that Plaintiff does not meet this standard because she does not point to any regulations which would demonstrate that compliance is a condition of payment. (Def.'s Mot. 23) (citing *Wilkins*, 659 F.3d at 309). Moreover, Defendant argues that "Trasylol was and is an FDA-approved medicine, and no provision of law requires the government to withhold payment of claims for FDA-approved drugs purportedly misbranded or marketed off-label, or to refuse payment as a direct purchaser." (Def.'s

Mot. 23). On the other hand, Plaintiff frames the issue before the Court as "whether knowledge of Trayslol's illegality in interstate commerce would or could have a tendency to influence the government's decision to directly purchase, or make payments in reimbursement of, the drug." (Pl.'s Opp'n. 18). However, Plaintiff points to no controlling law in support of that general position.

In addition, Simpson argues that Defendant's argument regarding the certifications addressed in *Wilkins* is inapplicable to her first two claims because they are based on the government directly purchasing or paying for Trasylol and, accordingly, do not involve certifications. (Pl.'s Opp'n. 19). Plaintiff generally points to provisions of the Federal Food, Drug, and Cosmetic Act and an accompanying regulation, which it contends rendered Trasylol misbranded, and thereby caused the government to illegally receive Trasylol. (Pl.'s Opp'n. 20) (citing 21 U.S.C. §§ 321(n), 352; 21 C.F.R. § 201.128). Without citing supporting authority, Plaintiff states that "[i]t is not reasonable to predict – which essentially is the Court's task here – that the government would knowingly break the law by purchasing Trasylol, nor that the government would knowingly pay for a drug that was illegal in interstate commerce." (Pl.'s Opp'n. 20). Finally, Plaintiff maintains that Bayer's conduct caused a drug with dangerous side effects to be used unnecessarily in surgeries and that Defendant's branding went to the central purpose of the FDA and misbranding statutes. (Pl.'s Opp'n. 22).

The Court agrees with Defendant, however, that it remains unclear how Defendant's alleged violations were a condition for payment. (Def.'s Reply 24). This is particularly the case because Plaintiff does not dispute that Trayslol was approved by the FDA at all times and that Plaintiff does not argue that Defendant caused claims to be

submitted that were not reimbursable. *See e.g. United States ex rel. Galmines v. Novartis Pharmaceuticals Corp.*, No. 06-3213, 2013 WL 2649704, at *11 (E.D.Pa June 13, 2013).

Bayer further argues that the "same deficiency dooms Simpson's counts based on the theory that Bayer's conduct led to uses of Trasylol that were not 'reasonable or necessary' (Counts 7 and 8)" for two reasons. (Def.'s Mot. 24-25). First, Simpson incorrectly contends that the uses are not "reasonable and necessary" because the off-label uses here are listed in a major drug compendium. (Def.'s Mot. 25). Second, "compliance with the 'reasonable and necessary' requirement is *not* a basis for the government to withhold payment, so long as the patient and provider reasonably understood the use to be 'reasonable and necessary.'" (Def.'s Mot. 25) (emphasis in original).

Plaintiff responds that "just as it is foreseeable that the government would not knowingly directly purchase or pay for a drug that is illegal, it is also foreseeable that the government would not knowing reimburse carriers, states or providers for a drug that is illegal." (Pl.'s Opp'n. 20). Further, Simpson argues that "[t]he issue is not whether [the government] has discretion to deny payment or seek damages, but whether [the government] has a *right* to" to do so and "whether doing so is a common response to the defendant's fraud." (Pl.'s Opp'n. 21).

The Government argues that a claim can be "false" for a number of reasons, including if it is not "covered" or "reimbursable" under a federal health care program. (Gov's SOI 2-3). Further, courts have held that when a healthcare provider prescribes a drug for a use that is not covered by federal programs such as Medicare or Medicaid, the provider's claim for reimbursement of that prescription is "false" under the FCA. (Gov's

SOI 4) (citing *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 51-53 (D. Mass. 2001) ("*Parke-Davis I*") ("The alleged FCA violation arises - not from unlawful off-label marketing activity itself - but from the submission of Medicaid claims for uncovered off-label uses induced by Defendant's fraudulent conduct."); *United States ex rel. Strom v. Scios*, 676 F. Supp. 2d 884, 891(N.D. Cal. 2009) ("Because the [Medicare] statute permits reimbursement only for 'reasonable and necessary' treatments, [an off-label prescription] in a context where it is not 'reasonable' or 'necessary' would be statutorily ineligible for reimbursement. This satisfies the FCA's requirement of a 'false' statement."); *see also Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975) (finding that submission of claims for services not covered by Medicare violated the FCA)).

Whether a use is covered under federal programs generally depends on whether medical items or services are reasonable and necessary. [16] The Court agrees with Bayer that "Simpson has not identified any uses of Trasylol that were not 'reasonable and necessary' . . . Courts and government reimbursement programs generally consider off-label uses to be medically accepted and thus 'reasonable and necessary if they are supported by a listing in a major drug compendium, and each of the off-label uses at issue here was supported by a listing in a major drug compendium." (Def.'s Response to Gov.'s SOI, 4). Indeed, in the context of their argument that off-label uses were

[16] As per the Medicare Benefit Policy Manual Chapter 15 § 50.42, reasonable and necessary uses include those that are "medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice." (Def.'s Mot. Ex. J); *see also United States ex rel. King v. Solvay*, 823 F. Supp. 2d 472, 510 (S.D. Texas 2011); *United States ex rel. McDermott v. Genentech*, No. 05-147, 2006 WL 3741920, at *13 (D.Me. Dec. 14, 206). Medicaid also ties coverage to whether an off-label use is medically accepted based on supportive citations in certain drug compendia. 42 U.S.C. § 1396r-8(k)(6). (*See also* Gov.'s SOI, 3).

unreasonable and unnecessary, Plaintiff submits that "off-label uses 'may be covered under Medicare if the carrier determines the use to be medically accepted.'" (Pl.'s Opp'n. 23) (quoting Medicare Benefits Policy Manual Chapter 15 § 50.4.2 (Def.'s Mot. Ex. J)). Plaintiff does not sufficiently allege that that was not the case here.[17] Rather, the Complaint alleges in a conclusory manner that "[a]s a drug with dangerous side effects being used in situations unsupported by the data, Trasylol was not 'reasonable or necessary for the diagnosis or treatment of illness' in such cases." (Counts VII, VIII).

To the extent that Plaintiff does not establish that the off-label uses were not reasonable and necessary, or tie the purportedly illegal claims to a condition for payment, the Court further agrees that the reasoning of *Wilkins* is applicable here. In that case, the Third Circuit wrote:

> We question the wisdom of regarding every violation of a Medicare regulation as a basis for a *qui tam* suit. Federal agencies are unquestionably better suited than federal courts to ensure compliance with Medicare marketing regulations. In the circumstances, we believe that by permitting *qui tam* plaintiffs to file suit based on the violation of regulations which may be corrected through an administrative process and which are not related directly to the Government's payment of a claim, courts unwisely would shift the burden of enforcing the Medicare regulations to themselves even though the administration of the vast and complicated Medicare program is best left to the administrators.

[17] In this regard, the Court declines to consider new arguments raised for the first time in Plaintiff's Reply to Bayer's Response to the Government's Statement of Interest. Plaintiff does not cite to any relevant portions of the Complaint which would support her assertions that Bayer's off-label uses were not reasonable and necessary or medically accepted. It is axiomatic that a Plaintiff may not amend a pleading through statements made in opposition to a motion to dismiss. *See Commonwealth of Pa. ex rel. Zimmerman v. PepsiCo, Inc.* 836 F.2d 173, 181 (3d Cir. 1988). The same applies to Simpson's statements here.

659 F.3d at 310-11 (internal citations omitted). Therefore, the Court dismisses without prejudice Plaintiff's claims premised on Bayer's alleged misbranding and promotion of off-label uses.[18]

In addition, in the context of its argument regarding causation, Defendant Bayer asserts that Plaintiff fails to allege a violation of the AKS. Specifically, Plaintiff's kickback allegations "describe fairly common financial transactions in the healthcare area: providing discounts on purchases, using consultants, hosting medical meetings, and giving grants to healthcare institutions. The [Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) ("AKS")] does not prohibit these types of payments." (Def.'s Mot. 32). Defendant contends that the AKS "requires the review of payments to determine if something *more* than fair market value has been provided for services, and if so, whether such remuneration was an improper reward or inducement to purchase [a] product." (Def.'s Mot. 32) (citing 42 U.S.C. § 1320a-7a(i)(6)). Notably, Defendant does not cite any case in support of its argument that Plaintiff fails to state a claim for violation of the AKS. (Def.'s Br. 33 & n. 25; *see also* Def.'s Resp. to the Gov.'s SOI, 7). Defendant's vague argument regarding the plausibility of Plaintiff's claim does not address the substance of the allegations of Plaintiff's complaint, namely that Bayer doled out kickbacks as part of its marketing scheme. In addition, the Court finds insufficient Bayer's contention that "some of the 'kickbacks' [Simpson] alleges appear to be lawful acts under statutory safe harbors." (Def.'s Mot. 33 n. 25). Therefore, the Court concludes that Defendant has not met its burden of demonstrating that dismissal is appropriate at this time.

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[18] Defendant also argues that Counts 2, 4, 6, and 8 fail because Simpson does not identify any express false certification of compliance with drug labeling laws, as required by § 3729(a)(2). The Court need not reach that argument, however, as it dismissed Plaintiff's claims based upon misbranding and off-label uses.

3. Rule 9(b) and Causation

The parties do not dispute that FCA claims must be pled with particularity in accordance with Rule 9(b). *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs.*, 149 F.3d 227, 234 (3d Cir. 1998); *accord Wilkins v. United Health Group, Inc.*, 659 F.3d at 301 n.9. "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). The purpose of the heightened pleading standard is to require the plaintiff to "state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the precise misconduct with which it is charged and to safeguard defendants against spurious charges of immoral or fraudulent behavior." *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir.1984); *Frederico v. Home Depot,* 507 F.3d 188, 200 (3d Cir.2007). To satisfy the heightened standard of Rule 9(b), a "plaintiff must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation." *Frederico v. Home Depot*, 507 F.3d at 200. In general, the complaint must describe the "who, what, when, where and how of the events at issue." *In re Rockefeller Ctr. Props. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir.2002) (citations and quotations omitted). However, "the law does not require specificity just for specificity's sake. The level of particularity required is sufficient details to put Defendants on notice of the 'precise misconduct with which they are charged.'" *Francis E. Parker Memorial Home, Inc. v. Georgia-Pacific LLC*, --- F. Supp. 2d ---, 2013 WL 2177974, at *11 (D.N.J. 2013) (quoting *Smajlaj, et al. v. Campbell Soup Co.*, 782 F. Supp. 2d 84, 104 (D.N.J. 2011)).

To establish a prima facie FCA violation under § 3729(a)(1), a plaintiff must show: "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *Wilkins*, 659 F.3d at 304-305 (quoting *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004)). "A prima facie case under § 3729(a)(2) requires that a plaintiff also show that the defendant made or used (or caused someone else to make or use) a false record in order to cause the false claim to be actually paid or approved." *Schmidt*, 386 F.3d at 242.[19]

Defendant argues that Simpson's claims should be dismissed under Federal Rule of Civil Procedure 9(b) because she has failed to plead her case with particularity. (Def.'s Mot. 31). Specifically, Defendant argues that the operative Complaint falls short because Simpson has not pled causation or false claims as to the following: (1) kickback allegations; (2) misbranding allegations; and (3) direct government purchases. (Def.'s Mot. 30-38).

Plaintiff opposes Bayer's assertion that a plaintiff must identify particular false claims at the pleading stage and argues that causation is not an element of an FCA claim. (Pl.'s Opp'n. 31-39). In its Statement of Interest, the Government also argues that whether a plaintiff must identify specific claims depends on the circumstances of the case. (Gov.'s SOI, 8) (citing *See United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 192 (5th Cir. 2009) ("That fraudulent bills were presented to the Government is the

[19] Although not necessary to the instant discussion, as Plaintiffs assert that Defendant violated § 3729(a)(7), the Court notes that "a claim under § 3729(a)(7) requires a plaintiff to prove a 'reverse false claim'; that is, that the defendant made or used (or caused someone else to make or use) a false record in order to avoid or decrease an obligation to the federal government." *Schmidt*, 386 F.3d at 242.

logical conclusion of the particular allegations in [relator's] complaint even though it does not include exact billing numbers or amounts."); *United States ex rel. Lusby v. Rolls Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009) ("We don't think it essential for a relator to produce the invoices (and accompanying representations) at the outset of the suit."); *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 732 (1st Cir. 2007)). Notably, the parties do not dispute that the Third Circuit has yet to weigh in on whether a plaintiff must identify representative samples at the pleading stage in order to properly plead an FCA claim with the specificity required by Rule 9(b). *See Wilkins*, 659 F.3d at 308. However, Plaintiff points to a number of cases where courts of appeals as well as district courts in this Circuit have held that it is not a *per se* requirement. (Pl.'s Opp'n. 36-8).[20] In light of the trend among courts of appeals and district courts in this Circuit, the Court declines to hold that a plaintiff must identify particular false claims at the pleading stage in every FCA case. Here, the alleged fraud or illegality is not tied to billing and is not

[20] Simpson points to the following cases decided by courts of appeals: *United States ex rel. Duxbury v. Ortho Biotech Prods.,L.P.*, 579 F.3d 13, 29 (1st Cir. 2009) ("[T]he district court held that the rule requires relators to 'provide details that identify particular false claims for payment that were submitted to the government.' This was error."); *accord United States v. Kaplan, Inc.*, No. 11-16651, 2013 WL 520418, at *2 (9th Cir. Feb. 13, 2013); *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, -- F.3d --, 2013 WL 136030, at *4 (4th Cir. Jan. 11, 2013); *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 472 (6th Cir. 2011); *United States v. Hawley*, 619 F.3d 886, 893-94 (8th Cir. 2010); *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010); *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d180, 190 (5th Cir. 2009). Plaintiff also points to the following cases decided by district courts in the Third Circuit: *United States ex rel. Underwood v. Genentech, Inc.*, 720 F. Supp. 2d 671, 677 (E.D. Pa. 2010) ("I do not see how Relator reasonably could be required to identify at the pleading stage a specific false claim submitted to the Government by a third party (perhaps a doctor or pharmacy)."); *accord United States ex rel. Budike v. PECO Energy*, Civ. A. No. 07-4147, 2012 WL 4108910, at *12 (E.D. Pa. Sept. 14, 2012); *United States ex rel. Streck v. Allergan, Inc.*, Civ. A. No. 08-5135, 2012 WL 2593791, at *14 (E.D. Pa. July 3, 2012); *United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, No. 04-186 ERIE, 2006 WL 2642518, at *7 (W.D. Pa. Sept. 13, 2006).

premised upon submission of a false claim by Bayer itself, but rather submission by third parties. Accordingly, at this stage of the litigation, Plaintiff need not identify a particular false claim submitted to the government. *See e.g. Galmines*, 2013 WL 2649704, at *11; *see also United States ex rel. Underwood v. Genetech, Inc.*, 720 F. Supp. 2d 671, 679 (E.D.Pa. 2010).

Defendant also argues that rather than plead causation, Plaintiff relies on mere conclusory statements which require dismissal under Rules 8, 12(b)(6), and 9. (Def.'s Mot. 31). As discussed above, Defendant argues that there are a number of gaps in Plaintiff's theory regarding kickbacks, most significantly, that rather than plead causation or identify false claims, she merely alleges:

> As a result [of Bayer's alleged acts], claims for payment for Avelox and related medical services *that were the product* of those kickbacks were false in implying that the Avelox and related medical services provided did not result from violations of the Anti-Kickback Statute.

(Def.'s Mot. 33) (quoting ¶385, citing ¶¶ 370, 377-78, 392-93) (alterations and emphasis added by Defendant). Therefore, Bayer argues that Simpson's claims are impermissibly speculative because she asks the Court to assume that some claims were the product of kickbacks, rather than identifying:

> A single alleged kickback recipient who submitted a claim to the government (as opposed to, for example, private insurer), let alone allege with particularity how compliance with the Anti-Kickback Statute was falsely certified *as to that recipient* and reimbursement *that recipient* is seeking. Indeed, she does not identify any claim for reimbursement supposedly tainted by kickbacks. And she does not plead the required causal nexus between the supposed claims submitted by these unidentified providers and Bayer's conduct.

(Def.'s Mot. 33-34).

In Opposition, Relator argues that causation is not an explicit element of a FCA prima facie case. (Pl.'s Opp'n. 31). Notwithstanding, Plaintiff argues that she sufficiently pleads causation for her false certification claims by:

> describing Bayer's broad scheme of illegal kickbacks to medical providers, intending to induce them to use and prescribe Trasylol and Avelox. (SAC ¶¶ 156-83 (Trasylol), ¶¶ 220-51 (Avelox).) She has explained how the Medicare and Medicaid certifications systems operate. (Id. ¶¶ 47-59.) And she has alleged facts that demonstrate that Bayer knew that its actions were in violation of the AKS. (Id. ¶¶ 73-77.)

(Pl.'s Opp'n. 36).

A plaintiff need not allege that falsity caused an actual loss to the government. *See United States v. Educ. Management Corp.*, 871 F.Supp.2d 433, 456 (W.D.Pa. 2012). In addition, as discussed above, under the circumstances presented in this case, Plaintiff need not identify a particular false claim submitted to the Government to withstand a motion to dismiss. The operative Complaint sufficiently alleges causation in light of Simpson's allegations, particularly those regarding Bayer's illegal kickback scheme engineered to induce medical providers to prescribe Trayslol and Avelox, which would inevitably cause false claims to be submitted to the government by healthcare providers. *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243-244 (3d Cir. 2004) (causation allegations were sufficient where plaintiff alleged that defendant "created and pursued a marketing scheme that it knew would, if successful, result in the submission by [healthcare providers] of compliance certifications required by Medicare that defendant knew would be false. If that conduct and this knowledge were proven at trial, a jury could conclude" that defendant knowingly caused the healthcare provider to file false claims.); *Wilkins*, 659 F.3d at 313 ("[I]n stating a plausible claim for relief at this stage of the proceedings for their complaint to survive a Rule 12(b)(6) motion, [a plaintiff] need

not allege a relationship between the alleged AKS violations and the claims appellees submitted to the Government").[21]

4. State and Local FCA Counts and the Statute of Limitations

As noted above, Simpson brings claims under the laws of 21 states, the District of Columbia, and New York City (Counts 13-35). Bayer argues that Simpson's state and local claims should be dismissed due to the following: (1) they are premature; (2) they fail for the same reasons that Simpson's federal FCA claims fail; and (3) Simpson's Trasylol claims should be dismissed under the first-to-file rule as to seventeen jurisdictions. In addition, Defendant argues that any surviving claims must be cabined by limitations periods and effective dates of statutes.

First, Defendant argues that "[n]o state, nor the District of Columbia nor New York City, has declined to intervene or granted Simpson authority to proceed. State FCAs (like the federal act, 31 U.S.C. § 3730(b)(2)), require that the government decline to intervention before the relator may proceed." (Def.'s Mot. 39) (citing Appendix B (collecting state statutes)). In response, Simpson contends, without citing any authority, that the State statutes cited by Bayer all refer to actions that were filed in State courts, not

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to a federal action where State claims are being tried by the exercise of supplemental jurisdiction. However, the Court agrees with Defendant that Plaintiff has not identified any authority which stands for the proposition that a federal court can ignore a statutory prerequisite for a claim under state substantive law. Therefore, the Court dismisses without prejudice Plaintiff's state and local claims.[22]

5. Employment Related Counts

1. Retaliation

To establish a claim for retaliation under § 3730(h), a relator must show that "(1) he engaged in protected conduct, (i.e., acts done in furtherance of an action under § 3730)"; and "(2) that he was discriminated against because of his protected conduct." *U.S. ex rel. Hefner v. Hackensack University Medical Ctr.*, 495 F.3d 103, 110–11 (3d Cir.2007) (internal citations omitted). Therefore, in order to establish that she was discriminated against as a result of her conduct in furtherance of a FCA suit, Simpson must demonstrate that Bayer had knowledge that she was engaged in protected conduct and Bayer's retaliation was motivated, at least in part, by her protected conduct. *Id.*

Bayer argues that Simpson has not alleged a claim under § 3730(h) because she does not plead that she (1) engaged in protected conduct or (2) that Bayer discriminated against her due to protected conduct. (Def.'s Mot. 44).[23] Bayer argues that she merely

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[22] The Court also deems it premature to consider Plaintiff's argument that the Court may have jurisdiction over the claims filed by Daniels if they fail for lack of subject matter jurisdiction because Plaintiff does argue that the Eastern District of Pennsylvania has determined that to be the case, and Defendant argues that the suit is still pending.

[23] In a footnote, Defendant also states that Plaintiff's New York CFA retaliation claim fails because the statute was not enacted until more than two years after Simpson's employment with Bayer ended and does not apply retroactively to retaliatory conduct. However, based on its limited treatment of this issue in its brief, Defendant does not meet its burden that dismissal is warranted.

expressed "concerns" to supervisors and Bayer employees regarding kickbacks and potential illegality and thereafter failed to receive certain assignments and was eventually terminated in connection with a broad work-force reduction. (Def.'s Mot. 44). Defendant urges that this was insufficient to place Bayer on notice of the possibility of FCA litigation and her "grumbling" about regulatory violations do not constitute protected conduct. (Def.'s Mot. 44).

The Court concludes that Plaintiff sufficiently pleads that she engaged in activities which constituted more than mere "grumbling" about regulatory violations and were sufficient to put Bayer on notice of her protected conduct. *United States ex rel. Yesudian v. Howard University*, 153 F.3d 731, 740-42 (D.C. Cir. 1998). As to protected conduct, the Third Circuit has explained:

> Determining what activities constitute "protected conduct" is a fact specific inquiry. But the case law indicates that "the protected conduct element ... does not require the plaintiff to have developed a winning qui tam action ... It only requires that the plaintiff engage[ ] in acts ... in furtherance of an action under [the False Claims Act]." ... Under the appropriate set of facts, these activities can include internal reporting and investigation of an employer's false or fraudulent claims."

Hutchins v. Wilentz, Goldman & Spitzer, 253 F.3d 176, 187 (3d Cir. 2001) (quoting *U.S. ex rel. Yesudian v. Howard University,* 153 F.3d 731, 739–40 (D.C.1998) (alteration in original)). Similarly, "[w]hether an employer is on notice of the 'distinct possibility' of False Claims Act litigation is also a fact specific inquiry." *Id.* at 189.

Here, Simpson spoke to her supervisors and members of Bayer's senior management on multiple occasions to inform them that she believed the relevant marketing practices were illegal and that she refused to participate in or help cover up what she believe to be illegal marketing tactics, including kickbacks. Plaintiff also

alleges that her discussions led to the involvement of in-house counsel. Simpson further alleges that as a result of those discussions, she was insulated from certain team activities and the business planning process, not given assignments or promotions for which she was qualified, and eventually terminated. In addition, Plaintiff alleges that she was informed that her choice to stand up to Mr. Horton was behind Bayer's decision to terminate her, notwithstanding that she warned Human Resources that her firing would be illegal. Accordingly, the Court concludes that Plaintiff sufficiently pleads a probable right to relief.[24]

2. Emotional Distress

The parties do not dispute that New Jersey's statute of limitations and Connecticut's substantive law apply to Simpson's emotional distress claims. Bayer argues that Plaintiff's emotional distress claims are barred by New Jersey's two year statute of limitations. (Def.'s Mot. 45) (citing N.J.S.A. 2A:14-2; *Pittston Co v. Sedgwick James of New York, Inc.*, 971 F. Supp. 915, 922 (D.N.J. 1997) (under N.J. conflict rule, forum's statute of limitations generally applies); *Fraser v. Bovino*, 317 N.J. Super. 23, 34 (1998) (two-year limitations period applies to emotional distress claims under N.J.S.A. 2A:14-2)). On the other hand, Simpson urges that those "claims are timely because they arise out of conduct described in Simpson's original Complaint, filed in 2005." (Pl.'s Opp'n. 53).

Federal Rule of Civil Procedure 15(c)(1)(B) provides, in relevant part, that: "An amendment to a pleading relates back to the date of the original pleading when the

[24] Stating a claim "does not impose a probability requirement at the pleading stage, but instead simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element." *Phillips v. County of Allegheny,* 515 F.3d 224, 234 (3d Cir.2008) (*quoting Twombly,* 550 U.S. at 556).

amendment asserts a claim or defense that arose out of the same conduct, transaction, or occurrence set out-or attempted to be set out-in the original pleading." "The touchstone of relation back is fair notice, because Rule 15(c) is premised on the theory that 'a party who has been notified of litigation concerning a particular occurrence has been given all the notice that the statutes of limitations were intended to provide.'" *Glover v. F.D.I.C.*, 698 F.3d 139, 146 (3d Cir. 2012).

To some extent, Plaintiff's emotional distress claims are premised on the same general conduct which gave rise to her retaliation claim, which was included in the original Complaint. However, the original Complaint did not contain allegations relating to the emotional distress allegedly suffered by Plaintiff, or many of the purported reasons she suffered emotional distress, such as being required to work on drugs despite knowledge of patient deaths or personal relationships which exacerbated that distress. Nor did the original Complaint allege facts that Bayer intentionally or knowingly caused Plaintiff's distress. Therefore, the Court concludes that Plaintiff's emotional distress claims do not relate back to Simpson's original Complaint. Accordingly, the Court dismisses those claims with prejudice.

IV. CONCLUSION

For the reasons set forth above, the Court grants in part and denies in part Defendant's motion to dismiss Simpson's Seventh Amended Complaint. The Court denies Defendant's motion with regard to Simpson's claims stemming from allegations of Bayer's kickback scheme and retaliation. The Court grants Defendants motion as to Relator's misbranding claims, state and local claims, and emotional distress. All of those

claims are dismissed without prejudice except Simpson's emotional distress claims, which are dismissed with prejudice. Relator may amend within thirty days.

Dated: 8/28/13

Jose L. Linares
United States District Judge